



Billing Code: 4120-01-U-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare & Medicaid Services

[Document Identifier: CMS-2567, CMS-10425, CMS-10417, CMS-10428, CMS-1500 (02/12), and CMS-1500 (08/05)]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare & Medicaid Services

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare & Medicaid Services (CMS), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the Agency's function; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. Type of Information Collection Request: Extension without change of a currently approved collection. Title of Information Collection: Deficiencies and Plan of Correction (CMS-2567) and Supporting Regulations contained in 42 CFR 488.18, 488.26, and 488.28. Use: Section 1864(a) of the Social Security Act requires that the Secretary use state survey agencies to conduct surveys to determine whether health care facilities meet Medicare and Clinical Laboratory Improvement Amendments participation requirements. The CMS-2567 form is the means by which the survey findings are documented. This section of the law further requires

that compliance findings resulting from these surveys be made available to the public within 90 days of such surveys. The CMS-2567 form is the vehicle for this disclosure. The regulations at 42 CFR 488.18 require that state survey agencies document all deficiency findings on a statement of deficiencies and plan of correction, which is the CMS-2567. 42 CFR 488.26 and 488.28 further delineate how compliance findings must be recorded and that CMS prescribed forms must be used.

The form is also used by health care facilities to document their plan of correction and by CMS, the states, facilities, purchasers, consumers, advocacy groups, and the public as a source of information about quality of care and facility compliance.

Form Number: CMS-2567 (OCN 0938-0391). Frequency: Yearly and occasionally.
Affected Public: Private Sector (Business or other for-profit and not-for-profit institutions).
Number of Respondents: 62,000. Total Annual Responses: 62,000. Total Annual Hours: 134,540. (For policy questions regarding this collection contact Angela Mason-Elbert at 410-786-8279. For all other issues call 410-786-1326.)

2. Type of Information Collection Request: New collection; Title of Information Collection: Evaluation of Patient Satisfaction and Experience of Care for Medicare Beneficiaries with End-Stage Renal Disease (ESRD): Impact of the ESRD Prospective Payment System (PPS) and ESRD Quality Incentive Program (QIP) ; Use: The Medicare Prescription Drug Improvement, and Modernization Act of 2003 (MMA) required the Secretary of Health and Human Services (HHS) to submit to Congress a report detailing the elements and features for the design and implementation of a bundled End-Stage Renal Disease Prospective Payment System, specifying that such a system should include the bundling of separately billed drugs,

clinical laboratory tests, and other items “to maximum extent feasible”. The Medicare Improvements for Patients and Providers Act of 2008 (MIPPA) directed the Secretary of HHS to implement a payment system under which a single payment is made to a provider of services or a renal dialysis facility for renal dialysis services in lieu of any other payment. The ESRD PPS combines composite rate dialysis services with separately billable services under a single payment adjusted to reflect patient differences in resource needs or case-mix. The MIPPA also stipulated the development of quality incentives for the ESRD program. CMS has established the End-Stage Renal Disease Quality Incentive Program (ESRD QIP) to address this provision of the legislation.

In order to assess the impact of the final rule (76 FR 627) on ESRD beneficiary experiences, satisfaction, and health outcomes, CMS is requesting OMB approval to obtain input on the effect of the final rule on our ESRD beneficiaries. The purpose of this data collection effort is to assess beneficiary satisfaction and experience of care in terms of access to services, quality of care, outcomes, and cost. This will be measured through telephone surveys with ESRD beneficiaries and through interviews with key stakeholders in the renal health care community. The information obtained from both the beneficiary respondents and key stakeholders will be used to provide an initial reporting of the ESRD PPS/QIP’s effects on beneficiary satisfaction and experience of care and to inform the Centers for Medicare & Medicaid Services (CMS) of the impact of the ESRD PPS/QIP on patient satisfaction and experience of care, including unintended consequences, for consideration of future modification of the programs.

Subsequent to the publication of the 60-day **Federal Register** notice (77 FR 27777), the

annual burden hours have decreased from 1,287 to 662. Early cognitive interview findings of the ESRD Beneficiary Survey submitted during the 60 day notice exhibited respondent complaints that the survey was too long and some participants had to hang up early because they were feeling sick. Medicare beneficiaries with end stage renal disease (ESRD) are very sick and unable to remain cognitively aware for 30 minutes. The ESRD Beneficiary Survey was significantly shortened so that the time necessary to interview a single participant was reduced from 30 to 15 minutes. Form Number: CMS-10425 (OCN: 0938-New); Frequency: Yearly; Affected Public: Individuals. Number of Respondents: 2,540. Number of Responses: 2,540. Total Annual Hours: 662. (For policy questions regarding this collection contact Steve Blackwell at 410-786-6852. For all other issues call 410-786-1326.)

3. Type of Information Collection Request: Extension of a currently approved collection; Title of Information Collection: Medicare Fee-for-Service Prepayment Medical Review; Use: The information required under this collection is requested by Medicare contractors to determine proper payment or if there is a suspicion of fraud. Medicare contractors request the information from providers or suppliers submitting claims for payment from the Medicare program when data analysis indicates aberrant billing patterns or other information which may present a vulnerability to the Medicare program. In addition, we are specifically soliciting public comments on the information collection burden that is associated with the currently approved information collection request. Form Number: CMS-10417 (OMB 0938-0969); Frequency: Occasionally; Affected Public: Private Sector (Business or other for-profit and Not-for-profit institutions); Number of Respondents: 2,220,434; Total Annual Responses: 2,220,434; Total Annual Hours: 1,105,560. (For policy questions regarding this collection contact Debbie Skinner

at 410-786-7480. For all other issues call 410-786-1326.)

4. Type of Information Collection Request: Extension of a currently approved collection;
Title: Pre-Existing Condition Insurance Plan (PCIP) Authorization to Share Personal Health Information; Use: On March 23, 2010, the President signed into law H.R. 3590, the Patient Protection and Affordable Care Act (Affordable Care Act), Public Law 111-148. Section 1101 of the law establishes a “temporary high risk health insurance pool program” (which has been named the Pre-Existing Condition Insurance Plan, or PCIP) to provide health insurance coverage to currently uninsured individuals with pre-existing conditions. The law authorizes HHS to carry out the program directly or through contracts with states or private, non-profit entities.

Reapproval of this package is being requested as a result of CMS, in its administration of the PCIP program, serving as a covered entity under the Health Insurance Portability and Accountability Act (HIPAA). Without a valid authorization, the PCIP program is unable to disclose information, with respect to an applicant or enrollee, about the status of an application, enrollment, premium billing or claim, to individuals of the applicant’s or enrollee’s choosing. The HIPAA Authorization Form has been modeled after CMS’ Medicare HIPAA Authorization Form (OMB control number 0938-0930) and is used by applicants or enrollees to designate someone else to communicate with PCIP about their protected health information (PHI).

Unless permitted or required by law, the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule (§ 164.508) prohibits CMS’ PCIP program (a HIPAA covered entity) from disclosing an individual’s protected health information without a valid authorization. In order to be valid, an authorization must include specified core elements and statements.

CMS will make available to PCIP applicants and enrollees a standard, valid authorization to enable beneficiaries to communicate with PCIP about their personal health information. This is a critical tool because the population the PCIP program serves is comprised of individuals with pre-existing conditions who may be incapacitated and need an advocate to help them apply for or receive benefits from the program. This standard authorization will simplify the process of requesting information disclosure for beneficiaries and minimize the response time for the PCIP program.

Each individual will be asked to complete the form which will include providing the individual's name, PCIP account number (if known), date of birth, what personal health information they agree to share, the length of time the individual agrees their personal health information can be shared, the names and addresses of the third party the individual wants PCIP to share their personal health information with, and an attestation that the individual is giving PCIP permission to share their personal health information with the third party listed in the form. This completed form will be submitted to the PCIP benefits administrator, GEHA, which contracts with CMS.

We estimate that it will take approximately 15 minutes per applicant to complete and submit a HIPAA Authorization Form to the PCIP program.

The federally-run PCIP program operates in 23 states plus the District of Columbia and receives an average of 35,000 enrollment applications per year. To estimate the number of PCIP applicants and enrollees who may complete an authorization, we looked at the percentage of individuals who request an authorization in Medicare as a baseline. Medicare estimates 3% of its population will submit an authorization per year. However, since the PCIP program caters to

an exclusive population comprised of individuals who have one or more pre-existing conditions, we believe it is likely we could receive double the percentage estimated by Medicare. Accordingly, PCIP estimates 6% (or 2,100) of its applicants and enrollees may submit an authorization per year.

It is estimated that up to 2,100 applicants and enrollees may submit an authorization annually. There is no cost to PCIP beneficiaries to request, complete, submit, or have the authorization form processed by PCIP. It should take approximately 15 minutes for a beneficiary to complete the authorization form. 15 minutes multiplied by 2,100 beneficiaries equals 525 hours. Form Number: CMS-10428(OCN#: 0938-1161); Frequency: Reporting – Once; Affected Public: individuals or households; Number of Respondents: 2,100; Total Annual Responses: 2,100; Total Annual Hours: 525. (For policy questions regarding this collection contact Laura Dash at 410-786-8623. For all other issues call 410-786-1326.)

5. Type of Information Collection Request: New collection; Title of Information Collection: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR Part 424, Subpart C; Use: The Form CMS-1500 answers the needs of many health insurers. It is the basic form prescribed by CMS for the Medicare program for claims from physicians and suppliers. The Medicaid State Agencies, CHAMPUS/TriCare, Blue Cross/Blue Shield Plans, the Federal Employees Health Benefit Plan, and several private health plans also use it; it is the de facto standard “professional” claim form.

Medicare carriers use the data collected on the CMS-1500 and the CMS-1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to

beneficiaries. The CMS-1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, the CMS-1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other federal programs (e.g., CHAMPUS/TriCare, Railroad Retirement Board (RRB), and Medicaid).

However, as the CMS-1500 displays data items required for other third-party payers in addition to Medicare, the form is considered too complex for use by beneficiaries when they file their own claims. Therefore, the CMS-1490S (Patient's Request for Medicare Payment) was explicitly developed for easy use by beneficiaries who file their own claims. The form can be obtained from any Social Security office or Medicare carrier.

Most recently, the National Uniform Claim Committee (NUCC) has revised the CMS-1500. The NUCC began revision work on the 1500 Claim Form, version 02/12 in 2009. The goal of this work was to align the paper form with some of the changes in the electronic Health Care Claim: Professional (837), 005010X222 Technical Report Type 3 (5010) and 005010X222A1 Technical Report Type 3 (5010A1). During the revision work, consideration was given to different approaches to revising the form. The NUCC decided to proceed with making "minor changes" to the current form, which was defined as no physical changes to the existing form lines or underlying layout of the form. Once the CMS-1500 (02/12) has been approved, the CMS-1500 (08/05) will be discontinued after a form runoff period during which both the CMS-1500 (08/05) and the CMS-1500 (02/12) can be used. Form Number: CMS-1500(02/12), CMS-1490-S (OMB#: 0938-New); Frequency: Reporting – On occasion; Affected Public: State, Local, or Tribal Government, Business or other-for-profit, Not-for-profit institutions; Number of Respondents: 1,448,346; Total Annual Responses: 988,005,045; Total Annual Hours:

21,418,336. (For policy questions regarding this collection contact Claudette Sikora at 410-786-5618. For all other issues call 410-786-1326.)

6. Type of Information Collection Request: Reinstatement without change of a previously approved collection; Title of Information Collection: Health Insurance Common Claims Form and Supporting Regulations at 42 CFR Part 424, Subpart C; Form Number: CMS-1500(08/05), CMS-1490-S (OMB#: 0938-0999); Use: The Form CMS-1500 answers the needs of many health insurers. It is the basic form prescribed by CMS for the Medicare program for claims from physicians and suppliers. The Medicaid State Agencies, CHAMPUS/TriCare, Blue Cross/Blue Shield Plans, the Federal Employees Health Benefit Plan, and several private health plans also use it; it is the de facto standard “professional” claim form.

Medicare carriers use the data collected on the CMS-1500 and the CMS-1490S to determine the proper amount of reimbursement for Part B medical and other health services (as listed in section 1861(s) of the Social Security Act) provided by physicians and suppliers to beneficiaries. The CMS-1500 is submitted by physicians/suppliers for all Part B Medicare. Serving as a common claim form, the CMS-1500 can be used by other third-party payers (commercial and nonprofit health insurers) and other Federal programs (e.g., CHAMPUS/TriCare, Railroad Retirement Board (RRB), and Medicaid).

However, as the CMS-1500 displays data items required for other third-party payers in addition to Medicare, the form is considered too complex for use by beneficiaries when they file their own claims. Therefore, the CMS-1490S (Patient’s Request for Medicare Payment) was explicitly developed for easy use by beneficiaries who file their own claims. The form can be obtained from any Social Security office or Medicare carrier. Frequency: Reporting – On

occasion; Affected Public: State, Local, or Tribal Government, Business or other-for-profit, Not-for-profit institutions; Number of Respondents: 1,448,346; Total Annual Responses: 988,005,045; Total Annual Hours: 21,418,336. (For policy questions regarding this collection contact Claudette Sikora at 410-786-5618. For all other issues call 410-786-1326.)

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web Site address at <http://www.cms.hhs.gov/PaperworkReductionActof1995>, or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to Paperwork@cms.hhs.gov, or call the Reports Clearance Office on (410) 786-1326.

To be assured consideration, comments and recommendations for the proposed information collections must be received by the OMB desk officer at the address below, no later than 5 p.m. on **[insert date 30 days after date of publication in the Federal Register.]**

OMB, Office of Information and Regulatory Affairs

Attention: CMS Desk Officer

Fax Number: (202) 395-6974

E-mail: OIRA_submission@omb.eop.gov

Dated: September 18, 2012 _____

Martique Jones

Director, Regulations Development Group, Division B

Office of Strategic Operations and Regulatory Affairs

[FR Doc. 2012-23365 Filed 09/20/2012 at 8:45 am; Publication Date: 09/21/2012]